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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,311	12/21/2000	Nicole Sucki-Foca	58332-B/JPW/AJM/DRM	9607

7590 09/30/2002
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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/30/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/746,311

Applicant(s)

SUCIU-FOCA ET AL.

Examiner

Michail A Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2001 and 21 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-42 and 66-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 27-42 and 66-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Restriction/Election fax*.

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DETAILED ACTION

Applicant's amendments, filed 09/10/01 and 12/21/00 (Paper Nos. 5 and 12), are acknowledged.

Claims 27-42 and 66-69 are pending.

Restriction Requirement

1. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in US on 06/15/2000. It is noted, however, that applicant has not filed a certified copy of the US00/16594 application as required by 35 U.S.C. 119(b).
3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 27-30, drawn to a vaccine comprising allospecific T suppressor cells, classified in Class 424 subclass 93.1.
 - II. Claims 31-32, drawn to a vaccine comprising xenospecific T suppressor cells, classified in Class 424 subclass 93.1.
 - III. Claims 33-35 and 37, drawn to a method of inducing anergic T helper cells wherein Ts are allospecific human suppressor CD8+ CD28- T cells, classified in Class 435, subclass 455.
 - IV. Claim 36, drawn to a method of inducing anergic T helper cells wherein Ts are xenospecific human suppressor CD8+ CD28- T cells, classified in Class 435, subclass 455.
 - V. Claims 38-40 and 42, drawn to a method generating a tolerogenic antigen presenting cell wherein Ts are allospecific human suppressor CD8+ CD28- T cells, classified in Class 435, subclass 325.

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VI. Claims 38, 39 and 41, drawn to a method generating a tolerogenic antigen presenting cell wherein Ts are xenospecific human suppressor CD8+ CD28- T cells, classified in Class, subclass 325.

VII. Claims 66 and 67, drawn to a method of determining the appearance of Ts cells wherein Ts are xenospecific human suppressor CD8+ CD28- T cells, classified in Class 435, subclass 326.

VIII. Claims 68 and 69, drawn to a method of determining the appearance of Ts cells wherein Ts are allospecific human suppressor CD8+ CD28- T cells, classified in Class 435, subclass 326.

4. Groups I and II are different products. Vaccine comprising allospecific T suppressor cells and vaccine comprising xenospecific T suppressor cells differ with respect to their structures and physicochemical properties; therefore each vaccine is patentably distinct.

5. Groups III - VIII are different methods. These inventions are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

7. Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

7.1. If Group III or IV is elected, applicant is required to elect a specific method of inducing anergic T helper cells wherein the monocyte inhibitory receptor is selected from the group recited in Claim 34 .

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These species are distinct because the methods of inducing anergic T helper cells wherein the monocyte inhibitory receptor is selected from the group recited in Claim 34, differ with respect to method steps and the endpoint of the method; thus each specific method employing a specific monocyte inhibitory receptor represents patentably distinct subject matter. Furthermore, the examination of specific monocyte inhibitory receptor recited in the claim 34 in the methods of inducing anergic T helper cells would require different searches in the scientific literature.

7.2. If Group V or VI is elected, applicant is required to elect a specific method of generating a tolerogenic antigen presenting cell wherein the monocyte inhibitory receptor is selected from the group recited in Claim 39.

These species are distinct because the methods of generating a tolerogenic antigen presenting cell wherein the monocyte inhibitory receptor is selected from the group recited in Claim 39, differ with respect to method steps and the endpoint of the method; thus each specific method employing a specific monocyte inhibitory receptor represents patentably distinct subject matter. Furthermore, the examination of specific monocyte inhibitory receptor recited in the claim 39 in the methods of generating a tolerogenic antigen presenting cell would require different searches in the scientific literature.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

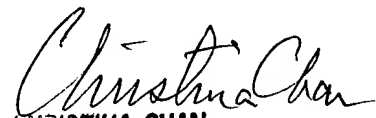
8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
September 30, 2002


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600